4910-62U

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 40

[Docket OST-99-6578]

RIN 2105-AD02

Procedures for Transportation Workplace Drug and Alcohol Testing Programs; Technical Amendments

AGENCY: Office of the Secretary, DOT.

ACTION: Final Rule

SUMMARY: The Department of Transportation is making a series of technical amendments to its drug and alcohol testing procedural rule, which goes into effect August 1, 2001. The purpose of these technical amendments is to clarify certain provisions of the rule and address omissions or problems which have been called to our attention since the publication of the final rule in December 2000.

EFFECTIVE DATES: This rule is effective August 1, 2001.

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SUPPLEMENTARY INFORMATION:

The Department of Transportation published revised procedures for its drug and alcohol testing program (49 CFR Part 40) on December 19, 2000 (65 FR 79462). This revised rule goes into effect, in its entirety, on August 1, 2001, replacing the previous version of Part 40. The new Part 40 is a comprehensive revision of the Department's testing procedures, making numerous and detailed substantive and organizational changes in the regulation. Not surprisingly for a document of this magnitude, we have noticed – and interested persons have called to our attention – instances in which the text of various sections of the regulation should be clarified or errors, omissions, or problems should be corrected.

This technical amendments document is intended to make these clarifications and corrections. The technical amendments were prepared with the intention of going into effect on August 1, 2001, so that users of the regulation will have the opportunity to use the amended version of the regulation without any delay. In the event that publication of the rule does not occur until after August 1, we request that interested parties be guided by the amended provisions of the rule, which we will have posted on our docket and web site by that date. In particular, we emphasize the Department's intention that validity testing remain voluntary at this time. Because we realize that regulated parties will have had little time to

incorporate these technical amendments, the Department, in its implementation and enforcement work, will provide a reasonable time to permit parties to make necessary changes in their procedures to comply with these amendments.

§40.3 Definitions

The Department is adding a new definition of "invalid drug test." This term is used in the new Federal Custody and Control Form (CCF) that becomes mandatory on August 1, but was not previously defined in Part 40. This definition is also expected to be included in the forthcoming Department of Health and Human Services (HHS) proposed amendments to their Mandatory Guidelines for drug testing.

In the definition of "designated employer representative (DER)," we are making a clarification by explicitly adding the function of "causing employees to be removed from these [i.e., safety-sensitive] functions." This addition is to cover the situation where the DER does not personally and directly remove the individual from safety-sensitive functions, but, for example, calls the individual's supervisor, who effects the actual removal.

§40.27 May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?

Part 40 states that service agents cannot require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the DOT drug or alcohol testing process. We inadvertently omitted language applying this same prohibition to employers. Lately, we have become aware that some employers and others are forcing employees to sign such documents. We want to clarify that no one can do so either on their own or a service agent's behalf. This new section and a parallel change in §40.355 provide this

clarification.

§40.33 What training requirements must a collector meet?

In new §40.208, the Department is changing the procedure for handling a situation in which a collector fails to record the specimen temperature. Since this mistake is no longer one that will require cancellation of a test, error correction training will not apply in that case. The purpose of the amendment to §40.33(c)(2) is to clarify that we intend all monitors (i.e., persons who make sure that collector trainees successfully complete the mock collections required by the rule) to have successfully completed qualification training for collectors, even if they have had a year's training experience or a train the trainer course.

§40.45 What form is used to document a DOT urine collection?

The Department has become aware that employers and collection sites, in some cases, are having a very difficult time obtaining copies of the new CCF that becomes mandatory on August 1, 2001. There may be some confusion among laboratories and other parties concerning whether DOT and HHS really mean that all Federal collections beginning August 1 must be conducted on the new form. The Department has added a paragraph to this section to emphasize that use of the new form is mandatory and that participants must stop using the old form.

This new paragraph provides that participants must not use a non-Federal form or an expired Federal form (like the old CCF) to conduct a DOT urine collection. Laboratories, C/TPAs and other parties that distribute CCFs to employers, collection sites, or other customers must not send any more copies of the old CCF to these participants. Parties who distribute forms must also affirmatively notify other participants that they must not use the expired Federal form.

The Department is also making changes to §§40.83, 40.203, and 40.205 concerning

the requirement to use the new CCF and corrective action that must be taken if the old CCF is used.

In addition, we are aware that some employers may wish to use C/TPAs to receive and maintain CCFs that come directly from the collection site. When this is the case – and we emphasize that this is the employer's choice, not the C/TPA's – the employer may use the C/TPA's mailing address in place of its own. Other employer information, such as name, telephone, and fax number, must remain on the CCF. The entry would read like this: Joe's Trucking Company; Phone 202- 555-5555; (fax) 202-555-5556; c/o CTPA's name and address.

§40.47 May employers use the CCF for non-Federal collections or non-Federal forms for DOT collections?

We have changed the word "non-DOT" to "non-Federal" to avoid confusion. The CCF is a joint DOT-HHS product that may be used for Federal drug testing programs subject to the HHS Mandatory Guidelines as well as to the DOT drug testing program.

§40.65 What does the collector check for when the employee presents a specimen?

Section 40.65 (c)(3) describes a situation where an employee refuses to provide another specimen where required. The current rule requires the collector to first notify the DER and then discard the specimen. This procedure should be reversed, i.e., the collector should discard the specimen first and then notify the DER. Otherwise the collector, who may not be able to get hold of the DER right away, would have to retain the urine specimen until such time that the DER is contacted. Also the reference to §40.191(a)(3) is inappropriate for this paragraph and has been corrected to refer to §40.191(a)(4).

§40.67 When and how is a directly observed collection conducted?

Section 40.67(d)(2) directs the collector to "explain to the employee the reason under this part for a directly observed collection under paragraph (c)(2) through (4) of this section." However, there is no paragraph (4). Additionally, paragraph (c)(1) should be included in the collector's explanation of why an observed collection is being conducted, i.e., because the employer required it; the employee, if not told by the employer, is certainly entitled to know this and the collector would have that information. A corrected reference is needed in paragraph (c)(1). Lastly, the collector will inform the employee of the reason for a direct observation collection if the collector knows the reason. If all the collector knows is that the employer ordered the direct observation collection, then that is all the information that the collector will be able to provide the employee.

When a collector learns that a directly observed test should have occurred, but did not, it is the collector's responsibility to correct the omission.
For example, suppose the initial specimen was out of temperature range, but the collector forgot to require a directly observed recollection. When the laboratory points out this problem to the collector, the collector would contact the employer. The employer, in turn, would contact the employee and direct the employee to undergo an immediate recollection under direct observation, even though some time may have passed since the original collection.

§40.69 How is a monitored collection conducted?

There have been some questions as to whether or not we meant to change the meaning of "medical professional" mentioned at §40.69 with respect to someone acting as a collection monitor. We did not. We still want doctors, nurses, and licensed medical technicians to be able to be monitors even if not the same gender, and we do not believe secretaries, receptionists, or records clerks are appropriate to

perform this function (unless of the same gender as the donor). If there is any doubt about the qualifications of others, such as an Emergency Medical Technician or a phlebotomist, the "litmus test" would be whether or not that individual is licensed or certified to practice as a medical professional in a state (i.e., approved by state action). If they meet that requirement, they would be allowed to be opposite-gender monitors. In paragraph (c), we are correcting the language to refer to the "monitor" rather than the "observer."

§40.71 How does the collector prepare the specimens?

Section 40.71 tells the collector how to prepare the specimen; it does not state what to do with any "left over" urine. There have been questions about the employee being able to take the "excess" urine with him/her, if any adulteration tests could be performed, or if any additional medical tests could be conducted on the excess specimen. This new paragraph clarifies these matters and incorporates an existing DOT interpretation that excess urine can be used in clinical urinalysis (e.g., specific gravity, protein, glucose) if the DOT specimen is collected in conjunction with a physical examination required by a DOT agency.

§40.73 How is the collection process completed?

Paragraph (a)(9) of this section mentions that the collector must fax or otherwise transmit the appropriate CCF copies to the MRO and DER. While we do not believe a regulatory text is change is necessary to make the point, we want to clarify that we view documents sent by fax as originals for purposes of this section. For example, the collector may fax the MRO copy of the CCF to the MRO. Since the MRO now has what we regard as an original, the collector could discard the MRO copy 30 days later.

§40.83 How do laboratories process incoming specimens?

We have revised this section to clarify the handling of certain problems concerning collections. As provided in new §40.208 below, we are no longer requiring the cancellation of a test because the collector omitted checking the temperature box and did not include a comment concerning the omission in the remarks section of the CCF. While this error still must be corrected, we do not believe it is necessary to cancel the test, since this is an error that does not diminish the rule's protections for the fairness of the testing process to the employee.

In addition, this section is changed be consistent with the clarification of the responsibilities of laboratories, C/TPAs and other parties to distribute and use only the new CCF. For three months, until the end of October 2001, use of expired "old" CCF, will not result in cancellation or rejection of a test, even if an appropriate correction is not made. Beginning November 1, the laboratory must report this situation (i.e., expired form used, correction not made) as "rejected for testing" with the appropriate remarks. We note that this change in timing applies only to use of the expired Federal CCF. When a non-Federal form is used at any time, the error must be corrected or the test must be rejected.

§40.89 What is validity testing, and are laboratories required to conduct it?

When the Department published its final rule in December 2000, we anticipated that HHS would amend its Mandatory Guidelines for drug testing establishing final requirements for validity testing by HHS-certified laboratories. HHS is continuing to work on this project, but the HHS amendment will not be published by August 1, 2001. The Department believes that it is advisable to wait until HHS has completed its amendment to make validity testing mandatory for all DOT specimens. Consequently, we are changing the language of paragraph (b) of this section to eliminate the requirement that laboratories conduct validity tests on

each DOT specimen. In its place, we are inserting language from our existing regulation providing that laboratories are authorized to conduct validity testing. This means that no change in validity testing will take place on August 1, 2001. We will amend this section again to mandate validity testing when HHS issues its final amendment.

§40.97 What do laboratories report and how do they report it?

Current §40.97(a) limits reporting to one result. We have already seen incidents where multiple results can occur because of adulterants. Recently one laboratory had a confirmed cocaine positive, but an adulterant prevented the laboratory from obtaining a satisfactory result for marijuana (neither negative, positive or adulterated). The final result should have been "positive – cocaine" as well as "invalid – with remark." By adding "or more" to the introductory text of paragraph (a), we are clarifying that it is proper to report such a multiple result.

The changes to paragraph (b)(1)(i) and (2) are designed to clarify the information to be provided on an electronic results report. The MRO needs to know where the test was performed. Since some laboratories have multiple laboratory sites, a name of the laboratory on the electronic report will not suffice to identify where the test was performed. HHS has indicated that the MRO's name and the certifying scientist's name would help laboratory inspectors who will be comparing electronic results with CCFs. The MRO name is also needed to ensure that the report goes to the right person. The Certifying Scientist's name is also needed in case the MRO needs to contact the laboratory for additional information and communication. The collector's name and phone number are needed in case someone needs to contact the collector for information or to take corrective action. Laboratories have been utilizing electronic reports since the outset of the program. Many of these reports contain information that is not contained on the CCF – the

"official " report. Since it is likely that the electronic results report will replace the CCF for the majority of negative reports, additional information should no longer appear on the electronic report.

§40.121 Who is qualified to act as an MRO?

There have been questions about when the first round of CEU hours and refresher training are required for previously trained MROs and BATs/STTs, respectively. The Department did not intend to have people who had already met qualification training requirements to face an immediate CEU or refresher-training requirement as soon as the regulations went into effect. Therefore, we are clarifying this section to specify that all MROs who were trained and examined before August 1, 2001 have until August 1, 2004 to complete their first round of CEUs. Likewise BATs/STTs who completed qualification training before January 1, 1998 would have until January 1, 2003, to complete refresher training, and we have amended §40.213 to this effect.

§40.127 What are the MRO's functions in reviewing negative test results?

We have corrected paragraph (g) by inserting the word "perform," which had been omitted. We also added a sentence to provide instructions on how to complete the CCF when a negative result is cancelled.

§40.129 What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid test results?

The current §40.129 does not contain instructions on completing the CCF when the MRO cancels a positive, adulterated, substituted, or invalid drug test report. This amendment provides clarified instructions on how the MRO should complete the CCF in this circumstance.

§40.131 How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?

We have been asked whether §40.131(d) means that the employee can contact the MRO at his or her leisure, just as long as it is within the next 72 hours. We are clarifying the provision to direct the employer to tell the employee to contact the MRO immediately. The employee would not violate the rule by not doing so, however. Of course, if the employee fails to contact the MRO within 72 hours, the MRO may declare the test a "non-contact positive." This amendment would also direct the employer to warn the employee of this consequence.

§40.135 What does the MRO tell the employee at the beginning of the verification interview?

Part 40 requires that MROs must report the use of any legally prescribed medication that could make the employee medically unqualified or pose a significant safety risk. Before doing so, however, this section tells MRO to contact the employee's physician to determine if the medication could be changed to one that does not make the employee unqualified to perform safety sensitive functions. We believe that it is likely to be easier and faster for the employee to contact his or her own physician and instruct that physician to contact the MRO. This would be more efficient than to require that the MRO repeatedly call the other physician. Employees can greatly assist the likelihood of this conversation by explaining their desire and motivation to their own treatment physician, and instructing that physician to contact the MRO on their behalf.

In addition, because the employee's use of the medication can pose a safety problem immediately, we believe that the contact with the prescribing physician should occur after, rather than before, the provision of information to the employer. To facilitate this process, the revised paragraph (e) of this section gives the employee 5 days to have his or her physician contact the MRO for this purpose. If the prescribing physician comes up with a prescription that will obviate the safety problem, the MRO would so inform the employer.

§40.149 May the MRO change a verified positive test result or refusal to test?

The Department has received a number of questions about the provision of this section, which provides, in its present form, that the MRO is the only person authorized to change a verified test result. Most of the questions concerned the effect of this provision on the authority of arbitrators, grievance examiners, etc. to review test results.

The Department makes the MRO the key person in determining the disposition of a non-negative laboratory result. The MRO is directed to bring his or her professional training and experience to bear on questions such as whether there is a legitimate medical explanation for a positive, adulterated, or substituted test result. The Department believes strongly that the medical judgment of the MRO on these questions should not be overturned by arbitrators, employers, or other participants in the drug testing program. Consequently, we have clarified paragraph (c) to emphasize that MROs have sole authority to make medical judgments about drug test results and that arbitrators and other participants in the system do not have authority to overturn these judgments.

This is not to say that an arbitrator is precluded from requiring a test result to be cancelled on other grounds (e.g., a fatal flaw in the chain of custody, the failure

of the MRO to provide an opportunity for the employee to present evidence of an alleged legitimate medical explanation, the denial of the right to have a split specimen tested). But an arbitrator could not decide, in the face of an MRO's judgment that there was not a legitimate medical explanation, that the employee had presented a legitimate medical explanation. This rule is intended to prevent such a substitution of judgment about a matter committed to the expertise of the MRO.

§40.151 What are MROs probibited from doing as part of the verification process?

Despite a clear explanation of the present §40.151(b) in the preamble, some MROs have misunderstood the present provision to be more sweeping than intended, and to constitute a sort of gag rule on MROs concerning contacts with collectors. The objective of this provision is not to preclude discussions between MROs and collectors. It is to protect MROs from being cast in the role of judge and jury in "he said/she said" disputes between employees about what occurred during the collection.

For example, suppose the employee tells the MRO that the collector left the open collection container unguarded and unobserved in a public space. The collector just as strongly denies the allegation. The MRO is not in a good position to evaluate the facts of the dispute or the credibility of the employee and collector. That is a function best left to other decisionmakers, such as arbitrators or the courts. Based on language in the final rule's preamble, paragraph (b) has been rewritten to focus on this point. Note that this paragraph focuses on disputes: nothing in the paragraph precludes an MRO from taking corrective action in a situation in which it is undisputed that an error took place (e.g., the collector and employee agree that a mistake requiring correction was made).

§40.155 What does the MRO do when a negative or positive test result is also dilute?

The current 40.155(c) instructs MROs in handling dilute test results – both positive and negative. Laboratories are provided instructions for reporting two categories of test results in 40.97 -- negative results and non-negative results. The requirements of 40.155(c) treat a negative-dilute result as a non-negative result (by requiring that the MRO receive Copy 1 from the laboratory). A negative-dilute result is still a negative result and to change the laboratory reporting requirements may connote undue suspicion on the result. The Department places negative and negative-dilute test results in the negative reporting category. All other results are considered non-negative. Effective and efficient notification can be made to the employer for a negative-dilute result in the same manner that notification is made for a negative result. Any further action on a negative-dilute (see §40.197) would be a function of the employer's policy.

40.163 How does the MRO report drug test results?

Commenters on the Part 40 proposed rule advocated greater use of electronic means to transmit negative results from MROs to employers. In the final rule preamble, we said that we agreed. One area in which greater reliance on electronic methods appears workable is the treatment of negative test reporting in this section.

Allowing for electronic reporting of negatives by MROs is consistent with the direction in which we have headed allowing more utilization of electronic capabilities (e.g., 40.97) by laboratories. However, current §40.163 does not specifically allow anything special for electronic reports for negatives as the preamble suggested we favored; in fact, reporting requirements in current §40.163

reference all reports being “in writing.” We have modified this section to remove this obstacle to electronic reporting of negatives.

A related change involves duplicate instructions of §§40.127 and 40.163 . Currently, both require MRO to initial or sign the CCF. The second initial/signing has been removed from §40.163.

§40.167 How are MRO reports of drug results transmitted to employers?

The Department is revising paragraph (c) of this section to clarify reporting requirements in view of the greater authorization for electronic reporting of negative results. In addition, we are adding a new paragraph (e) to parallel the prohibition of reversals of MROs medical judgments as provided in §40.149(c).

§40.187 What does the MRO do with split specimen laboratory results?

The Department is adding two new paragraphs to this section to fill gaps that have been called to our attention since we published the final rule. The first is a situation in which, for example, the primary specimen tests positive for a drug but the split specimen test is invalid (see new paragraph (e)). In this case (parallel to the situation in which the split specimen is unavailable for testing) the test is cancelled and the employer must require the employee to undergo an immediate recollection under direct observation.

The second is a hopefully rare situation in which the primary specimen tests positive for a drug, and the split specimen does not reconfirm the presence of the drug but the laboratory determines that an adulterant is present (see new paragraph (f)). In this case, we do not have a reconfirmed positive drug test. On the other

hand, we do have a laboratory finding that, were it made with respect to the primary specimen, would be the basis of a refusal result.

We do not believe it is sound policy, and consistent with our safety objectives, to ignore this adulteration result. On the other hand, we believe it is important to provide appropriate due process protections for employees in this situation. Consequently, the MRO will contact the employee and ask whether there is any legitimate medical explanation for the presence of the adulterant in the split specimen. If there is a legitimate medical explanation, the entire test is cancelled. If not, the MRO reports the test to the employee and DER as a refusal. The employee will have 72 hours to request a test of the primary specimen to determine if the adulterant is present there as well. Except that this is a test of the primary specimen, taking place at the laboratory that originally tested the primary specimen, this test is intended to parallel the testing of the split specimen in the more usual type of case. If the test of the primary specimen reconfirms the presence of the adulterant found in the split specimen, then the refusal result is reconfirmed. If not, then the test is cancelled and the "split invalid" procedure of paragraph (e) applies.

§40.191 What is a refusal to take a DOT drug test, and what are the consequences?

In paragraph (a) of this section, we are making a number of changes to clarify the application of the refusal provisions of the rule to pre-employment testing. In the case of pre-employment testing, it is very possible for applicants to fail to appear for a test for a number of legitimate reasons (e.g., took another job, decided they did not want to change their present job, decided they didn't want to work for a particular employer). In this situation, we believe it would be unfair to visit the consequences of a refusal (e.g., having to complete the return-to-duty process, certificate actions under some DOT agency regulations) on the applicant (§40.191(a)(1)).

For example, suppose someone has applied to both Company A and Company B for a job. Both companies tell him that they want to offer him a job, but that he will have to have a pre-employment test before they can actually hire him. Each company schedules the employee for a pre-employment test. Before the tests occur, the employee decides that since Company A will pay him more, he prefers to work for Company A. He takes the pre-employment test scheduled by Company A, but not the one scheduled by Company B, since he is no longer interested in working for Company B. In this situation, we would not view the individual as having refused a test by not having attended Company B's scheduled test.

In addition, in the pre-employment test context, there can be situations in which an employee could legitimately leave a collection site before the test actually commences (e.g., there is a long wait for the test and the employee has another obligation). By the commencement of the test, we mean the actions listed in §40.63(c), in which the collector or employee selects a collection container. Once the collection has commenced, the donor has committed to the process, and must complete it. If the employee then leaves before the process is complete, or takes another action listed in this section as a refusal, the consequences of a refusal attach. However, if the employee leaves the site before the test commences, then the employee is in the same situation as someone who does not appear at all for the pre-employment test. The consequences of a refusal do not attach in this situation (§40.191(a)(2) and (3)).

If a medical evaluation or examination is required as part of a pre-

employment drug test process, the requirement could raise questions of consistency with the employment provisions of the Americans with Disabilities Act, as implemented by Equal Employment Opportunity Commission (EEOC) regulations and guidance. It is not the drug test itself that raises these issues, only the medical examination or evaluation that follows it (e.g., in the context of a "shy bladder" situation). To avoid raising ADA issues, we have added a sentence providing that an employee is deemed to have refused to test on the basis of not undergoing such an examination only if the pre-employment test is conducted following a contingent offer of employment (§40.191(a)(7)).

We are also making two minor changes to this section. In paragraph (a)(1), we are adding a reference to consistency with DOT agency drug regulations, which may establish time frames for sending employees for random or other tests. In paragraph (d), we have deleted a potentially confusing reference to use of a separate document and clarify that the employee's name should be entered on Copy 2 of the CCF.

We also note that there may be a few situations in which an employee may legitimately not go the collection site for a pre-employment test.

§40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

For consistency with other parts of the rule, we have deleted the word "working" from the phrase "five working days." We have also added a requirement

to document on the CCF the time at which the three-hour period to drink fluids begins and ends in a "shy bladder" situation. The intent of this requirement is to avoid questions about whether the proper amount of time was given to the employee. If the collector omits this information, it does not result in the cancellation of the test (see §40.209). We have also clarified the rule by saying that an employee who leaves the collection site before the "shy bladder" collection process is complete has refused to test.

§40.195 What happens when an individual is unable to provide a sufficient amount of urine for a pre-employment, follow-up, or return-to duty test because of a permanent or long-term medical condition?

We have added follow-up tests to this provision since they, like pre-employment and return-to-duty tests, require employees to have a negative test result in order to meet regulatory requirements for safety-sensitive employment.

§40.203 What problems cause a drug test to be cancelled unless they are corrected?

There are two changes to this section. We are no longer treating the failure of the collector to check the temperature box and to annotate the remarks section concerning temperature as a flaw that results in cancellation unless it is corrected. This is still an error in the collection that needs to be corrected (see §40.208 below), but it is not a mistake that undermines the protections afforded the employee. Checking the temperature is important as a means of detecting attempts

to adulterate or substitute the specimen, but omitting this step does not make the process less fair for the employee.

The second change underlines the importance of using the new CCF, which becomes mandatory on August 1, 2001. Beginning on that date, the old Federal CCF will have expired, and its use is no longer authorized. It will have the same status as a non-Federal form. That is, if a non-Federal or expired Federal form is used for a test, the test must be cancelled unless the error is corrected as provided in §40.205. We are concerned about reports that, almost a year after use of the new form was authorized, many employers and collection sites are having difficulty obtaining copies of the new CCF from their laboratories and/or C/TPAs. We are providing a 90-day grace period during which the failure to correct the use of an obsolete Federal form will not result in the cancellation of a test. After that, participants who fail to correct the use of the expired Federal form will bear the consequences of a cancelled test.

§40.205 How are drug test problems corrected?

We have amended paragraph (b)(2) to specify that this correction procedure applies to the use of expired Federal forms as well as to non-Federal forms. The content of the correction document has also been clarified.

§40.208 What problem requires corrective action but does not result in the cancellation of a test?

This is a new section focusing on the temperature box checkoff issue described in connection with §40.203 above. This section requires correction of the error (i.e., through an MFR). However, the error does not result in the cancellation of a test. When a collector makes this error, the collector is not required to undergo error correction training. However, the employer, C/TPA, collection site, etc. responsible for the collector should take appropriate steps to ensure that the collector does not repeat the mistake.

§40.209 What procedural problems do not result in the cancellation of a test and do not require corrective action?

We have modified the title of this section to avoid confusion with the title of new §40.208. We also have added reference to service agents as a party who are subject to potential consequences for errors that do not result in the cancellation of tests, through the "PIE" provisions of Subpart R of the rule.

§40.213 What training requirements must STTs and BATs meet?

The final rule inadvertently changed the number of mock tests BAT and STT trainees had to complete. We have amended this section to maintain the status quo with respect to the testing requirements established by the DOT Model Course. In addition, to avoid requiring some previously trained BATs and STTs to complete refresher training too quickly, we have added a sentence saying individuals trained before January 1, 1998, have until January 1, 2003, to get refresher training.

§40.225 What form is used for an alcohol test?

To make the transition to use of the new alcohol testing form easier, we are making use of the new ATF mandatory as of February 1, 2002. Use of the new form is authorized now. To maintain consistency between use of the old form and the instructions in new Part 40, employees should be asked to sign Statement 4 only if their test result is .02 or higher. We have also modified paragraph (b)(4) to clarify that there are a number of options for the coloring of ATFs.

§40.229 What devices are used to conduct alcohol screening tests?

Only alcohol screening devices (ASDs) on the National Highway Traffic Safety Administration's Conforming Products List (CPL) may be used for DOT alcohol screening tests. This is a necessary, but not sufficient, condition for using an ASD. It is possible that there may be devices added to the CPL that do not have instructions for their use incorporated in Part 40. Until and unless instructions for properly using the device in the context of DOT alcohol testing appear in Part 40, it is not permissible to use such a device for DOT alcohol tests. The Department is adding a sentence to this section making this point explicit.

§ 40.253 What are the procedures for conducting an alcohol confirmation test?

We have substituted the word "unique" for the word "sequential" to avoid any unnecessary conflict with EBTs that may not, as such, provide sequential

numbers. Unique numbers for each test, even if not sequential, provide sufficient identification of the test.

§40.261 What is refusal to take an alcohol test, and what are the consequences?

We have modified §40.261(a)(1)-(3) to be consistent with §40.191, with respect to refusals of pre-employment tests.

§40.281 Who is qualified to act as a SAP?

In the final rule's preamble discussion concerning qualification training for substance abuse professionals (SAPs), the Department commented that "…the Department does not believe that this examination needs to be a formally designed and validated examination, " suggesting that the examination could be simpler than the examinations administered by existing MRO training groups (65 FR 79507). In discussions with participants in the drug and alcohol testing program, this approach has been questioned. As a result of this discussion, we have re-thought this position. No regulatory text changes are needed as a result of this change in our thinking.

It is now the Department's policy that a nationally-recognized SAP training organization that constructs an examination should have the examination validated by an outside test evaluation organization (as MRO groups have done for their tests) or by an effective peer review. The validation process would include a discussion of test items, areas of knowledge tested, and the effectiveness with which the test items measure the areas of knowledge involved. It should also include a psychometric review that evaluates how the items and questions are structured. The review should suggest modifications to the examination, if needed, to improve its

quality.

We emphasize that we are not requiring that an outside organization actually develop, administer, score, or grade the test, but simply review and evaluate the examination to make sure it was a good measure of what SAP trainees are supposed to learn. For this reason, we believe the cost of the process is modest. The information we have learned from sources in the testing business suggests that one could expect a review of the kind we envision for around $10,000.

§40.329 What information must laboratories, MROs, and other service agents release to employees?

Part 40 requires a Substance Abuse Professional (SAP) to provide an employee, upon request, a copy of SAP reports. We have heard concerns expressed by SAPs and employers that providing a report containing the follow-up testing plan will give the employee the number and frequency of follow-up testing. We do not believe that an employee returning to duty following a rule violation should have access to the follow-up testing plan, which could lessen the deterrent effect of follow-up tests. Therefore, we are directing SAPs to remove follow-up testing information from SAP reports they provide to employees.

§40.331 To what additional parties must employers and service agents release information?

The Department is concerned that DOT agency representatives may not be able to effectively inspect or audit electronically stored records, data, and

information. Therefore, the Department will require that all records and data be presented in such a way that they can be easily reviewed. If electronic records do not meet this "auditable" standard, the electronic documentation must be changed into printed format. This is a reasonable requirement to impose on employers and other parties who take advantage of the greater flexibility and cost savings provided by opportunities for electronic data management permitted under Part 40. In addition, to avoid any possible confusion, we have specifically directed both employers and service agents to meet DOT agency timing requirements for production of records to inspectors or other DOT officials (e.g., two business days for FMCSA).

§40.333 What records must employers keep?

We have received questions asking whether the regulation is intended to require the retention of information concerning blind as well as employee specimens. We do intend for blind specimen records to be retained. To avoid potential uncertainty on this point, we have removed the word "employee" from paragraphs (a)(1)(i) and (ii) of this section, so that the language refers to all specimens. We have also added a new paragraph (e), which parallels the language discussed under §40.331 above concerning "auditable" electronic records.

§40.349 What records may a service agent receive and maintain?

We made this change for terminological consistency with §40.333(d).

§40.355 What limitations apply to the activities of service agents?

One of the limitations on service agent activities is a prohibition on requiring employees to sign consents, waivers etc. We have added a sentence to this paragraph to specify that no one else (e.g., an employer) can do so for the service agent. In addition, in response to comments on the DOT agency conforming rules, we have deleted the requirement for DOT agency rule authorization for C/TPAs to declare a refusal in the case of an owner-operator who fails to appear for a test.

§40.403 Must a service agent notify its clients when the Department issues a PIE?

We made this change for terminological consistency with other provisions of the rule.

Appendix F

We have added a few sections to the drug testing information list in this appendix to correspond to other changes we have made in Part 40 or to correct earlier omissions.

REGULATORY NOTICES AND ANALYSES

This rule is a non-significant rule both for purposes of Executive Order 12886 and the Department of Transportation's Regulatory Policies and Procedures. The Department certifies that it will not have a significant economic effect on a substantial number of small entities, for purposes of the Regulatory Flexibility Act.

The Department makes these statements on the basis that, as a series of technical amendments that correct or clarify existing regulatory provisions, this rule will not impose any significant costs on anyone. The costs of the underlying Part 40 final rule were analyzed in connection with its issuance in December 2000. Therefore, it has not been necessary for the Department to conduct a regulatory evaluation or Regulatory Flexibility Analysis for this final rule.

This rule imposes no information collection requirements for which Paperwork Reduction Act approval is needed. It has no Federalism impacts that would warrant a Federalism assessment. The amendments made in this rule are technical, corrective, and clarifying changes to an existing rule that went through an extensive public notice and

comment process. The amendments do not make significant substantive changes to Part 40, and we would not anticipate the receipt of meaningful comments on them. However, it is essential that these technical amendments take effect on August 1, 2001, with the rest of the new Part 40. Delaying these amendments for a prior comment period would be unnecessary and contrary to the public interest, as it would result in participants having to implement an uncorrected version of the rule and then make changes in the midst of implementing the new rule. For the same reasons, the Department has good cause to make the changes effective in less than 30 days.

List of Subjects in 49 CFR Part 40

Administrative practice and procedure, Alcohol abuse, Alcohol testing, Drug abuse, Drug testing, Reporting and recordkeeping requirements, Safety, Transportation

ISSUED THIS DAY OF JULY, 2001, AT WASHINGTON, D.C.

_____

Norman Y. Mineta

Secretary of Transportation

For the reasons set forth in the preamble, the Department of Transportation amends 49 CFR Part 40 as follows:

PART 40 - PROCEDURES FOR TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAMS

1. The authority citation for 49 CFR Part 40 continues to read as follows:

   Authority: 49 U.S.C. 102, 301, 322, 5331, 20140, 31306, and 45101 et seq.

2. Amend §40.3 as follows:

§40.3 What do terms used in this regulation mean?

* * * * *

a. In the definition of "Designated employer representative (DER)", add the words ", or cause employees to be removed from these covered duties," after the word "duties";

b. Add a definition of "Invalid drug test" in alphabetical order to read as follows:

Invalid drug test. The result of a drug test for a urine specimen that contains an unidentified adulterant or an unidentified interfering substance, has abnormal physical characteristics, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing or obtaining a valid drug test result.

* * * * *

3. In subpart B, redesignate §40.27 as §40.29, and add a new §40.27, to read as follows

§40.27 May an employer require an employee to sign a consent or release in connection with the DOT drug and alcohol testing program?

No, as an employer, you must not require an employee to sign a consent, release, waiver of liability, or indemnification agreement with respect to any part of the drug or alcohol testing process covered by this part (including, but not limited to, collections, laboratory testing, MRO and SAP services).

§40.33 [Amended]

4. Amend §40.33 (c)(2), introductory in the second sentence, to remove the words “an individual” and add in their place the words “a qualified collector”.

5. Amend §40.45 as follows:

a. In paragraph (a), revise the HHS web site address to read “(http://www.workplace.samhsa.gov)”.

b. Redesignate paragraphs (b), (c), and (d), as paragraphs (c), (d), and (e), respectively.

c. Add a new paragraph (b).

d. Add a sentence at the end of newly redesignated paragraph (c)(2) to read as follows:

§40.45 What form is used to document a DOT urine collection?

* * * * *

(b) You must not use a non-Federal form or an expired Federal form to conduct a DOT urine collection. As a laboratory, C/TPA or other party that provides CCFs

to employers, collection sites, or other customers, you must not provide copies of an expired Federal form to these participants. You must also affirmatively notify these participants that they must not use an expired Federal form (e.g., that beginning August 1, 2001, they may not use the old 7-part Federal CCF for DOT urine collections).

(c) * * *

(2) * * *

The employer may use a C/TPA's address in place of its own, but must continue to include its name, telephone number, and fax number.

* * * * *

6. Amend §40.47 by removing the word "non-DOT" and adding in its place the word "non-Federal" in the heading of the section, in paragraph (a), and in paragraph (b)(2).

7. Amend §40.65 by revising paragraph (c)(3) to read as follows:

§40.65 What does the collector check for when the employee presents a specimen?

* * * * *

(c) * * *

(3) In a case where the employee refuses to provide a specimen under direct observation (see § 40.191(a)(4)), you must discard any specimen the employee provided previously during the collection procedure. Then you must notify the DER as soon as practicable.

8. Amend §40.67 by revising paragraphs (c)(1) and (d)(2) and adding a new paragraph (m), to read as follows:

§40.67 When and how is a directly observed collection conducted?

* * * * *

(c) * * *

(1) You are directed by the DER to do so (see paragraphs (a) and (b) of this section); or

* * * * *

(d) * * *

(2) As the collector, you must explain to the employee the reason, if known, under this part for a directly observed collection under paragraphs (c)(1) through (3) of this section.

* * * * *

(m) As the collector, when you learn that a directly observed collection should have been collected but was not, you must inform the employer that it must direct the employee to have an immediate recollection under direct observation.

9. Amend §40.69 by revising paragraphs (b) and (c) to read as follows:

§40.69 How is a monitored collection conducted?

* * * * *

(b) As the collector, you must ensure that the monitor is the same gender as the employee, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor can be a different person from the collector and need not be a qualified collector.

(c) As the collector, if someone else is to monitor the collection (e.g., in order to ensure a same-gender monitor), you must verbally instruct that person to

follow the procedures of paragraphs (d) and (e) of this section. If you, the collector, are the monitor, you must follow these procedures.

* * * * *

10. Amend §40.71 by adding a new paragraph (b)(8), to read as follows:

§40.71 How does the collector prepare the specimens?

* * * * *

(b) * * *

(8) You must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: you may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a physical examination required by a DOT agency regulation. Neither you nor anyone else may conduct further testing (such as adulteration testing) on this excess urine and the employee has no legal right to demand that the excess urine be turned over to the employee.

11. Amend §40.83 by revising paragraphs (e) and (f); redesignating paragraphs (g) and (h) as paragraphs (h) and (i), respectively; and adding a new paragraph (g) to read as follows:

§40.83 How do laboratories process incoming specimens?

* * * * *

(e) You must inspect each CCF for the presence of the collector's signature on the certification statement in Step 4 of the CCF. Upon finding that the signature is omitted, document the flaw and continue the testing process.

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the flaw.

(2) You must then attempt to correct the flaw by following the procedures of §40.205(b)(1).

(3) If the flaw is not corrected, report the result as rejected for testing in accordance with §40.97(a)(3).

(f) If you determine that the specimen temperature was not checked and the ``Remarks'' line did not contain an entry regarding the temperature being outside of range, you must then attempt to correct the problem by following the procedures of §40.208.

(1) In such a case, you must continue your efforts to correct the problem for five business days, before you report the result.

(2) When you have obtained the correction, or five business days have elapsed, report the result in accordance with §40.97(a.

(g) If you determine that a CCF that fails to meet the requirements of §40.45(a) (e.g., a non-Federal form or an expired Federal form) was used for the collection), you must attempt to correct the use of the improper form by following the procedures of §40.205(b)(2).

(1) In such a case, you must retain the specimen for a minimum of 5 business days from the date on which you initiated action to correct the problem.

(2) During the period August 1 – October 31, 2001, you are not required to reject a test conducted on an expired Federal CCF because this problem is not corrected. Beginning November 1, 2001, if the problem(s) is not corrected, you must reject the test and report the result in accordance with §40.97(a)(3).

* * * * *

§40.89 [Amended]

12. Amend §40.89(b) by removing the word “must” and adding in its place the words “are authorized to”.

13. Amend §40.97 by revising the introductory text of paragraph (a) and paragraphs (b)(1)(i) and (b)((1)(ii) to read as follows:

§40.97 What do laboratories report and how do they report it?

(a) As a laboratory, you must report the results for each primary specimen tested as one or more of the following:

* * * * *

(b) * * *

(1) * * *

(i) If you elect to provide the laboratory results report, you must include the following elements, as a minimum, in the report format:

(A) Laboratory name and address;

(B) Employer's name (you may include I.D. or account number);

(C) Medical review officer's name;

(D) Specimen I.D. number;

(E) Donor's SSN or employee I.D. number, if provided; `

(F) Reason for test, if provided;

(G) Collector's name and telephone number;

(H) Date of the collection;

(I) Date received at the laboratory;

(J) Date certifying scientist released the results;

(K) Certifying scientist's name;

(L) Results (e.g., positive, adulterated) as listed in paragraph (a) of this section; and

(M) Remarks section, with an explanation of any situation in which a correctable flaw has been corrected.

(ii) You may release the laboratory results report only after review and

approval by the certifying scientist. It must reflect the same test result information as contained on the CCF signed by the certifying scientist. The information contained in the laboratory results report may not contain information that does not appear on the CCF.

* * * * *

14. Amend §40.121 by adding a new paragraph (d)(3), to read as follows:

§40.121 Who is qualified to act as an MRO?

* * * * *

(d) * * *

(3) If you are an MRO who completed the qualification training and examination requirements prior to August 1, 2001, you must complete your first increment of 12 CEU hours before August 1, 2004.

* * * * *

15. Amend §40.127 by revising the introductory text of paragraph (g) to read as follows:

§40.127 What are the MRO's functions in reviewing negative test results?

* * * * *

(g) Staff under your direct, personal supervision may perform the administrative functions of this section for you, but only you can cancel a test. If you cancel a laboratory-confirmed negative result, check the ``Test Cancelled'' box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the ``Remarks'' line, provide your name, and sign, initial or stamp and date the verification statement.

* * * * *

16. Amend §40.129 by redesignating paragraphs (d), (e), and (f) as paragraphs (e), (f), and (g) respectively, and by adding a new paragraph (d), to read as follows:

§40.129 What are the MRO's functions in reviewing laboratory confirmed positive, adulterated, substituted, or invalid test results?

* * * * *

(d) If you cancel a laboratory confirmed positive, adulterated, substituted, or invalid drug test report, check the ``test cancelled'' box (Step 6) on Copy 2 of the CCF, make appropriate annotation in the ``Remarks'' line, sign, provide your name, and date the verification statement.

* * * * *

17. Amend §40.131 by revising the introductory text of paragraph (d) to read as follows:

§40.131 How does the MRO or DER notify an employee of the verification process after a confirmed positive, adulterated, substituted, or invalid test result?

* * * * *

(d) As the DER, you must attempt to contact the employee immediately, using procedures that protect, as much as possible, the confidentiality of the MRO's request that the employee contact the MRO. If you successfully contact the employee (i.e., actually talk to the employee), you must document the date and time of the contact, and inform the MRO. You must inform the employee that he or she should contact the MRO immediately. You must also inform the employee of the consequences of failing to contact the MRO within the next 72 hours (see § 40.133(a)(2)).

* * * * *

18. Amend §40.135 by revising paragraph (e) to read as follows:

§40.135 What does the MRO tell the employee at the beginning of the verification interview?

* * * * *

(e) You must also advise the employee that, after informing any third party about any medication the employee is using pursuant to a legally valid prescription under the Controlled Substances Act, you will allow 5 days for the employee to have the prescribing physician contact you to determine if the medication can be changed to one that does not make the employee medically unqualified or does not pose a significant safety risk. If, as an MRO, you receive such information from the prescribing physician, you must transmit this information to any third party to whom you previously provided information about the safety risks of the employee's other medication.

19. Amend §40.149 by revising paragraph (c) to read as follows:

§40.149 May the MRO change a verified positive test result or refusal to test?

* * * * *

(c) You are the only person permitted to change a verified test result, such as a verified positive test result or a determination that an individual has refused to test because of adulteration or substitution. This is because, as the MRO, you have the sole authority under this part to make medical determinations leading to a verified test (e.g., a determination that there was or was not a legitimate medical explanation for a laboratory test result). For example, an arbitrator is not permitted to overturn the medical judgment of the MRO that the employee failed to present a legitimate medical explanation for a positive, adulterated, or substituted test result of his or her specimen.

20. Amend §40.151 by revising paragraph (b) to read as follows:

§40.151 What are MROs probibited from doing as part of the verification process?

* * * * *

(b) It is not your function to make decisions about factual disputes between the employee and the collector concerning matters occurring at the collection site that are not reflected on the CCF (e.g., concerning allegations that the collector left the area or left open urine containers where other people could access them).

* * * * *

§40.155 [Amended]

21. Amend §40.155 by removing paragraph (c) and redesignating paragraph (d) as new paragraph (c).

22. Revise §40.163 to read as follows:

§40.163 How does the MRO report drug test results?

(a) As the MRO, it is your responsibility to report all drug test results to the employer.

(b) You may use a signed or stamped and dated legible photocopy of Copy 2 of the CCF to report test results.

(c) If you do not report test results using Copy 2 of the CCF for this purpose, you must provide a written report (e.g., a letter) for each test result. This report must, as a minimum, include the following information:

(1) Full name, as indicated on the CCF, of the employee tested;

(2) Specimen ID number from the CCF and the donor SSN or employee ID number;

(3) Reason for the test, if indicated on the CCF (e.g., random, post-accident);

(4) Date of the collection;

(5) Date you received Copy 2 of the CCF;

(6) Result of the test (i.e., positive, negative, dilute, refusal to test, test cancelled) and the date the result was verified by the MRO;

(7) For verified positive tests, the drug(s)/metabolite(s) for which the test was positive;

(8) For cancelled tests, the reason for cancellation; and

(9) For refusals to test, the reason for the refusal determination (e.g., in the case of an adulterated test result, the name of the adulterant).

(d) As an exception to the reporting requirements of paragraph (b) and (c) of this section, the MRO may report negative results using an electronic data file.

(1) If you report negatives using an electronic data file, the report must contain, as a minimum, the information specified in paragraph (c) of this section, as applicable for negative test results.

(2) In addition, the report must contain your name, address, and phone number, the name of any person other than you reporting the results, and the date the electronic results report is released.

(e) You must retain a signed or stamped and dated copy of Copy 2 of the CCF in your records. If you do not use Copy 2 for reporting results, you must

maintain a copy of the signed or stamped and dated letter in addition to the signed or stamped and dated Copy 2. If you use the electronic data file to report negatives, you must maintain a retrievable copy of that report in a format suitable for inspection and auditing by a DOT representative.

(f) You must not use Copy 1 of the CCF to report drug test results.

(g) You must not provide quantitative values to the DER or C/TPA for drug or validity test results. However, you must provide the test information in your possession to a SAP who consults with you (see § 40.293(g)).

23. Amend §40.167 by revising paragraph (c), and adding a new paragraph (e), to read as follows:

§40.167 How are MRO reports of drug results transmitted to employers?

*** * * * ***

(c) You must transmit the MRO's report(s) of verified tests to the DER so that the DER receives it within two days of verification by the MRO.

(1) You must fax, courier, mail, or electronically transmit a legible image or copy of either the signed or stamped and dated Copy 2 or the written report (see §40.163(b) and (c)).

(2) Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.

* * * * *

(e) MRO reports are not subject to modification or change by anyone other than the MRO, as provided in §40.149(c).

24. Amend §40.187 by redesignating paragraphs (e) and (f) as paragraphs (g) and (h), respectively, and adding new paragraphs (e) and (f), to read as follows:

§40.187 What does the MRO do with split specimen laboratory results?

* * * * *

(e) *Failed to Reconfirm: Specimen Results Invalid.* (1) Report to the DER and the employee that both tests must be cancelled and the reason for cancellation.

(2) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) Using the format in Appendix D to this part, notify ODAPC of the failure to reconfirm.

(f) *Failed to Reconfirm: Split Specimen Adulterated.* (1) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated.

(2) Follow the procedures of §40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration.

(3) If you determine that there is a legitimate medical explanation for the adulterated test result, report to the DER and the employee that the test is cancelled. Using the format in Appendix D to this part, notify ODAPC of the result.

(4) If you determine that there is not a legitimate medical explanation for

the adulterated test result, take the following steps:

(i) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen also is present in the primary specimen.

(ii) Except that the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§40.153, 40.171, 40.173, 40.179, and 40.185.

(iii) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF .

(iv) If the test of the primary specimen reconfirms the adulteration finding of the split specimen, as the MRO you must report the test result as a refusal as provided in §40.187(a)(2).

(v) If the test of the primary specimen fails to reconfirm the adulteration finding of the split specimen, as the MRO you cancel the test. Follow the procedures of paragraph (e) of this section in this situation.

* * * * *

25. Amend §40.191 by revising paragraphs (a)(1), (2), (3), and (7) and the introductory text of paragraph (d), to read as follows as follows:

§40.191 What is a refusal to take a DOT drug test, and what are the

consequences?

(a) ***

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.61(a));

(2) Fail to remain at the testing site until the testing process is complete; *Provided*, That an employee who leaves the testing site before the testing process commences (see §40.63 (c)) for a pre-employment test is not deemed to have refused to test;

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations; *Provided,* That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see §40.63 (c)) for a pre-employment test is not deemed to have refused to test;

* * * * *

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under §40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment; or

* * * * *

(d) As a collector or an MRO, when an employee refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the CCF (including, in the case of the collector, printing the

employee's name on Copy 2 of the CCF), immediately notify the DER by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating a "shy bladder" condition or a claim of a legitimate medical explanation in a validity testing situation), you must notify the MRO, who in turn will notify the DER.

* * * * *

26. Amend §40.193 as follows:

a. Revise paragraphs (b)(2) and (b)(3)

b. In paragraph (c) introductory text, remove the word "working" before the word "days".

c. Add and revise paragraph (c)(2). The revisions read as follows:

§40.193 What happens when an employee does not provide a sufficient amount of urine for a drug test?

*** * * * ***

(b) * * *

(2) Urge the employee to drink up to 40 ounces of fluid, distributed reasonably through a period of up to three hours, or until the individual has provided a sufficient urine specimen, whichever occurs first. It is not a refusal to test if the employee declines to drink. Document on the Remarks line of the CCF (Step 2), and inform the employee of, the time at which the three-hour period begins and ends.

(3) If the employee refuses to make the attempt to provide a new urine specimen or leaves the collection site before the collection process is

complete, you must discontinue the collection, note the fact on the ``Remarks'' line of the CCF (Step 2), and immediately notify the DER. This is a refusal to test.

* * * * *

§40.195 [Amended]

27. Amend §40.195 by adding, in the section heading and in the introductory text of paragraph (a), after the word “pre-employment”, the words “, follow-up,”.

28. Amend §40.203 by revising paragraphs (b) and (d)(3) to read as follows:

§40.203 What problems cause a drug test to be cancelled unless they are corrected?

* * * * *

(b) The following is a “correctable flaw” that laboratories must attempt to correct: The collector’s signature is omitted on the certification statement on the CCF.

* * * * *

(d) * * *

(3) The collector uses a non-Federal form or an expired Federal form for the test. This flaw may be corrected through the procedure set forth in §40.205(b)(2), provided that the collection testing process has been conducted in accordance with the procedures of this part in an HHS-certified laboratory. During the period August 1 – October 31, 2001, you are not required to cancel a test because of the use of an expired Federal form. Beginning November 1, 2001, if the problem is not corrected, you must cancel the test.

29. Amend §40.205 by revising paragraph (b)(2) to read as follows:

§40.205 How are drug test problems corrected?

* * * * *

(b) * * *

(2) If the problem is the use of a non-Federal form or an expired Federal form, you must provide a signed statement (i.e., a memorandum for the record). It must state that the incorrect form contains all the information needed for a valid DOT drug test, and that the incorrect form was used inadvertently or as the only means of conducting a test, in circumstances beyond your control. The statement must also list the steps you have taken to prevent future use of non-Federal forms or expired Federal forms for DOT tests. For this flaw to be corrected, the test of the specimen must have occurred at a HHS-certified laboratory where it was tested consistent with the requirements of this part. You must supply this information on the same business day on which you are notified of the problem, transmitting it by fax or courier.

* * * * *

30. Add a new §40.208, to read as follows:

§40.208 What problem requires corrective action but does not result in the cancellation of a test?

(a) If, as a laboratory, collector, employer, or other person implementing the DOT drug testing program, you become aware that the specimen temperature on the CCF was not checked and the “Remarks” line did not contain an entry regarding the temperature being out of range, you must take corrective action, including securing a memorandum for the record explaining the problem and taking appropriate action to ensure that the problem does not recur.

(b) This error does not result in the cancellation of the test.

(c) As an employer or service agent, this error, even though not sufficient to cancel a drug test result, may subject you to enforcement action under DOT agency regulations or Subpart R of this part.

31. Amend §40.209 as follows:

a. Revise the heading of the section.

b. In paragraph (c), after the word “employer” add the words “or service agent”.

c. In paragraph (c), after the word “regulations” add the words “or action under Subpart R of this part”.

The revision reads as follows:

§40.209 What procedural problems do not result in the cancellation of a test and do not require correction?

* * * * *

32. Amend §40.213 as follows:

a. Amend the introductory text of paragraph (c) by removing the words “three consecutive error-free mock tests” and adding in their place the words “seven consecutive error-free mock tests (BATs) or five consecutive error-free tests (STTs)”.

b. Amend paragraph (e) by adding a sentence at the end of the paragraph, to read as follows:

§40.213 What training requirements must BATs and STTS meet?

* * * * *

(e) * * * If you are a BAT or STT who completed qualification training before January 1, 1998, you are not required to complete refresher training until January 1, 2003.

* * * * *

33. Amend §40.225 as follows:

a. In paragraph (a), after the word “test” and add the words “beginning February 1, 2002”.

b. Revise paragraph (b)(4) to read as follows:

§40.225 What form is used for an alcohol test?

*** * * * ***

(b) * * *

(4) You may use an ATF in which all pages are printed on white paper. You may modify the ATF by using colored paper, or have clearly discernable borders or designation statements on Copy 2 and Copy 3. When colors are used, they must be green for Copy 2 and blue for Copy 3.

* * * * *

34. Amend §40.229 by adding a new sentence after the first sentence to read as follows:

§40.229 What devices are used to conduct alcohol screening tests?

* * *

You may use an ASD that is on the NHTSA CPL for DOT alcohol tests only if there are instructions for its use in this part. * * *

§40.253 [Amended]

35. Amend §40.253(c) by removing the word “sequential” and adding in its place the word “unique”.

36. Amend §40.261 as follows:

a. Revise paragraphs (a)(1) – (a)(3).

b. In paragraph (a)(6), remove the words “§40.241(b)(7));” and add, in their place, the words “§40.241(g) and §40.251(d));”

The revisions read as follows:

§40.261 What is a refusal to take an alcohol test, and what are the consequences?

(a) * * *

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear for a test when called by a C/TPA (see §40.241(a));

(2) Fail to remain at the testing site until the testing process is complete; *Provided*, That an employee who leaves the testing site before the testing process commences (see §40.243(a)) for a pre-employment test is not deemed

to have refused to test;

(3) Fail to provide an adequate amount of saliva or breath for any alcohol test required by this part or DOT agency regulations; *Provided* ,that an employee who does not provide an adequate amount of breath or saliva because he or she has left the testing site before the testing process commences (see §40.243(a)) for a pre-employment test is not deemed to have refused to test;

* * * * *

37. Amend §40.329 by revising paragraph (c) to read as follows:

§40.329 What information must laboratories, MROs, and other service agents release to employees?

* * * * *

(c) As a SAP, you must make available to an employee, on request, a copy of all SAP reports (see §40.311). However, you must redact follow-up testing information from the report before providing it to the employee.

38. Amend §40.331 by revising paragraphs (b)(2) and (c)(2), and adding new paragraphs (b)(3) and (c)(3), to read as follows:

§40.331 To what additional parties must employers and service agents release information?

* * * * *

(b) * * *

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents / documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.

(3) All items in paragraph (b)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.

(c) * * *

(2) All written, printed, and computer-based drug and alcohol program records and reports (including copies of name-specific records or reports), files, materials, data, documents / documentation, agreements, contracts, policies, and statements that are required by this part and DOT agency regulations. You must provide this information at your principal place of business in the time required by the DOT agency.

(3) All items in paragraph (c)(2) of this section must be easily accessible, legible, and provided in an organized manner. If electronic records do not meet these standards, they must be converted to printed documentation that meets these standards.

* * * * *

39. Amend §40.333 as follows:

a. In paragraphs (a)(1)(i) and (a)(1)(ii), remove the word “employee”.

b. In paragraph (d), remove the word “working” and add in its place the word “business”.

c. Add a new paragraph (e), to read as follows:

§40.333 What records must employers keep?

*** * * * ***

(e) If you store records electronically, where permitted by this part, you must ensure that the records are easily accessible, legible, and formatted and stored in an organized manner. If electronic records do not meet these criteria, you must convert them to printed documentation in a rapid and readily auditable manner, at the request of DOT agency personnel.

§40.349 [Amended]

40. Amend §40.349(e) by adding the word “business” after the word “two”.

§40.355 [Amended]

41. Amend §40.355 as follows:

a. Add a sentence at the end of paragraph (a).

b. In paragraph (j)(1), remove the words “You are authorized by a DOT agency regulation to do so,” and add the word “You” in their place.

The addition reads as follows:

§40.355 What limitations apply to the activities of service agents?

*** * * * ***

(a) *** * *** No one may do so on behalf of a service agent.

*** * * * ***

§40.403 [Amended]

42. Amend §40.403(a) by removing the word “working” and adding in its place the word “business”.

43. Amend Appendix F to Part 40 by revising the list entitled “Drug Testing Information, to read as follows:

Appendix F to Part 40 – Drug and Alcohol Testing Information that C/TPAs May Transmit to Employers

* * * * *

Drug Testing Information

§40.25: Previous two years’ test results
§40.35: Notice to collectors of contact information for DER
§40.61(a): Notification to DER that an employee is a "no show" for a drug test
§40.63(e): Notification to DER of a collection under direct observation
§40.65(b)(6) and (7) and (c)(2) and (3): Notification to DER of a refusal to provide a specimen or an insufficient specimen
§40.73(a)(9): Transmission of CCF copies to DER (However, MRO copy of CCF must be sent by collector directly to the MRO, not through

the C/TPA.)

§40.111(a): Transmission of laboratory statistical report to employer

§40.127(f): Report of test results to DER

§§40.127(g), 40.129(d), 40.159(a)(4)(ii); 40.161(b): Reports to DER that test is cancelled

§40.129 (d): Report of test results to DER

§40.129(g)(1): Report to DER of confirmed positive test in stand-down situation

§§40.149(b): Report to DER of changed test result

§40.155(a): Report to DER of dilute specimen

§40.167(b) and (c): Reports of test results to DER

§40.187(a) – (f) Reports to DER concerning the reconfirmation of tests

§40.191(d): Notice to DER concerning refusals to test

§40.193(b)(3): Notification to DER of refusal in shy bladder situation

§40.193(b)(4): Notification to DER of insufficient specimen

§40.193(b)(5): Transmission of CCF copies to DER (not to MRO)

§40.199: Report to DER of cancelled test and direction to DER for additional collection

§40.201: Report to DER of cancelled test

* * * * *